Annex. Prevention of Zika virus transmission by substances of human origin

In order to prevent Zika virus transmission through substances of human origin (SoHO), a range of measures is possible: informing donors about the infection, temporary deferral of donors based on the recent travel history to affected areas, and medical diagnosis of Zika virus infection. The use of pathogen-inactivated blood components and tissues, or laboratory screening of donors/donations for Zika virus disease are recommended in affected areas. At present, no laboratory screening assays are commercially available.

WHO is currently working on international reference preparations for Zika virus RNA and for Zika virus antibodies to be used for the comparative evaluation of both diagnostic and screening assays [75]. A regularly updated list and maps of areas/countries affected with Zika virus are available from the ECDC website.

Non-affected areas

Blood and tissue establishments should update their donor information materials and health questionnaires to comply with the proposed safety measures.

Persons with diagnosed with Zika virus infection, except sperm donors, may be accepted for blood, cell and tissue donation 28 days after cessation of symptoms. Sperm donors who have been infected with Zika virus should be deferred from donation for six months unless the semen tests negative for Zika virus RNA by nucleic acid testing (NAT).

Health authorities should implement a precautionary deferral of asymptomatic blood, cell and tissue donor, except sperm donors, for 28 days after return from an affected area. Asymptomatic sperm donors should be deferred for six months after return unless the semen tests negative for Zika virus by NAT [53,54]. NAT testing could also be used to reinstate blood, cell and tissue donors.

Donors who had sexual contact with a man who has been diagnosed with Zika virus infection or with a man who travelled or lived in a Zika-affected area during the six months prior to the sexual contact may only donate blood, cells and tissues after at least 28 days after the last sexual contact [76].

A possible Zika virus infection in an organ donor should not automatically lead to exclusion from the donation, except when the organ recipient is a pregnant woman [77]. The risk of Zika virus transmission through a living donor should be assessed during a pre-donation evaluation and balanced against the benefits of the transplantation for each potential recipient. If indicated, donations by living donors at risk of Zika virus infection could be postponed for 28 days after possible exposure or cessation of Zika virus disease symptoms. The laboratory testing of deceased organ donors at risk for the presence of Zika virus infection may contribute to transplantation safety and unnecessary organ loss.

SoHO donors should be encouraged to inform SoHO facilities if they develop symptoms compatible with Zika virus infection within two weeks after donation.

In unaffected areas with competent vectors for Zika virus, a preparedness plan for the prevention and control of outbreaks of Zika virus infection should be developed to ensure the safety and continuity of SoHO supplies. This plan should also specify the conditions which necessitate the implementation of SoHO safety measures.

National competent authorities may authorise the importation of SoHO from affected areas, but only if the cells and tissues tested negative for Zika virus by NAT or if they were inactivated/sterilised by a validated method.

The multiple pathogen reduction steps used in the manufacturing process of plasma-derived medicinal products have been shown to be robust in the removal of enveloped viruses. Data from model viruses were confirmed with the inactivation of West Nile virus and chikungunya virus [78,79]. For this reason, and in line with the regulations for West Nile virus deferral in EU Directive 2004/33/EC [80], it is not essential to exclude blood donors who have returned from affected areas from donating plasma for fractionation. It is also not essential to screen plasma for fractionation which was donated in areas affected by Zika fever.

All measures related to urine donation (deferring urine donors from affected areas, screening of urine donors and urine donations) should be based on a risk assessment aimed at ensuring the viral safety of urine-derived medicinal products.

Affected areas

As 80% of humans infected with Zika virus are asymptomatic, donor deferral measures based on fever will be of limited value in detecting viraemic donors. Experience from previous flavivirus outbreaks shows that blood and tissue establishments may consider the following:

- Temporary interruption of donations in affected areas and importation of blood components from unaffected parts of the country.

- Pathogen inactivation for plasma, platelets [81-84] and some tissues. The amotosalen UV method has been demonstrated to inactivate Zika virus in plasma [85].
- Screening of all donated blood and all donors of cells and tissues for the presence of Zika virus RNA by NAT.
- Individual assessment of organ donors, carefully weighing the benefits against the risks. Laboratory testing of living and deceased organ donors for the presence of Zika virus infection may contribute to transplantation safety and unnecessary organ loss.

SoHO establishments should update their donor information materials and health questionnaires to comply with the safety measures.